(8) A written commitment to label, distribute, and promote the new animal drug only in accordance with the index entry;

(9) The name and address of the contact person or permanent-resident U.S. agent; and

(10) A draft Freedom of Information summary which includes the following information:

(i) A general information section that contains the name and address of the requestor and a description of the drug, route of administration, indications, and recommended dosage.

(ii) A list of the names and affiliations of the members of the qualified expert panel, not including their addresses or other contact information.

(iii) A summary of the findings of the qualified expert panel concerning the target animal safety and effectiveness of the drug.

(iv) Citations of all publicly-available literature considered by the qualified expert panel.

(v) For an early life stage of a food-producing minor species animal, a human food safety summary.

(c) Upon specific request by FDA, the requestor shall submit the information described in §516.141 that it submitted to the qualified expert panel. Any such information not in English should be accompanied by an English translation.

### §516.147 Refuse to file a request for addition to the index.

(a) If a request for addition to the index contains all of the information required by §516.145(b), FDA shall file it, and the filing date shall be the date FDA receives the request.

(b) If a request for addition to the index lacks any of the information required by §516.145, FDA will not file it, but will inform the requestor in writing within 30 days of receiving the request as to what information is lacking.

### §516.149 Denying a request for addition to the index.

(a) FDA will deny a request for addition to the index if it finds the following:

(1) The same drug in the same dosage form for the same intended use is already approved or conditionally approved;

(2) On the basis of new information, the new animal drug no longer meets the conditions for eligibility for indexing;

(3) The request for indexing fails to contain information required under the provisions of §516.145;

(4) The qualified expert panel fails to meet any of the selection criteria listed in §516.141(b);

(5) The written report of the qualified expert panel and other information available to FDA is insufficient to permit FDA to determine that the benefits of using the new animal drug for the proposed use in a minor species outweigh its risks to the target animal, taking into account the harm caused by the absence of an approved or conditionally-approved new animal drug for the minor species in question;

(6) On the basis of the report of the qualified expert panel and other information available to FDA, the benefits of using the new animal drug for the proposed use in a minor species do not outweigh its risks to the target animal, taking into account the harm caused by the absence of an approved or conditionally-approved new animal drug for the minor species in question; or

(7) The request contains any untrue statement of a material fact or omits material information.

(b) When a request for addition to the index is denied, FDA will notify the requestor in accordance with §516.153.

### §516.151 Granting a request for addition to the index.

(a) FDA will grant the request for addition of a new animal drug to the index if none of the reasons described in §516.149 for denying such a request applies.

(b) When a request for addition of a new animal drug to the index is granted, FDA will notify the requestor in accordance with §516.153.

### §516.153 Notification of decision regarding index listing.

(a) Within 180 days after the filing of a request for addition of a new animal drug to the index, FDA shall grant or